AMPCARE

OCT 15 2012

5. 510(k) SUMMARY – K121483

Submitter:	AMPCARE, LLC 1201 Richardson Drive, Suite 280 Richardson, Texas 75080
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Date Prepared:	May 17, 2012 *revised September 13, 2012*
Trade Name:	Reusable Cutaneous Electrode
Common Name:	Cutaneous Electrode
Classification Name:	GXY 882.1320 Electrode, Cutaneous

Predicate Devices:

K915333	GXY	Labeltape Meditect, Inc. (Uni-Patch / Covidien)
K080386	GXY	Columbia Scientific Development, LLC
K852267	GXY	Axelgaard Manufacturing Company, Ltd.
K083756	GXY	SelectiveMed Components, Inc. (Guardian)

Device Description: The new AMPCARE 50709 Series Electrodes device is a family of cutaneous electrodes with various shapes and sizes, which are similar in design and construction to several predicate cutaneous electrodes. AMPCARE electrodes are non-sterile, self-adhering, and are for multiple use by a single patient, available with either pin/socket or snap connections.

Statement of Intended Use: AMPCARE 50709 Series of cutaneous electrodes are intended to be used to apply electrical stimulation current to the patient's skin. Example electrical stimulation current applications of these electrodes are: a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief, b) Electrical muscle stimulation (EMS) for neck muscle stimulation, c) Functional electrical stimulation (FES), d) Galvanic stimulation, e) Microcurrent electrical nerve stimulation (MENS), f) Interferential (IF) stimulation, and g) Neuromuscular electrical stimulation (NMES), including for muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Summary of Technological Characteristics: The new AMPCARE device is designed in accordance with the general design approach of the predicate devices referenced above. Specifically, each electrode in the AMPCARE 50709 Series is constructed with a non-conductive top layer, conductive center layer and adhesive bottom layer. The plastic liner at the bottom of the electrode is peeled away just prior to placement on the patient, consistent with the four predicate devices. The pin/socket connector version of the new device will be provided with a lead wire that is 21 CFR 898 compatible, containing a female recessed socket for electrical connection.

Summary of Non-Clinical Testing:	Dispersion testing has demonstrated that the new AMPCARE device has uniform current distribution with no evidence of "hot spots" that could cause patient discomfort or injury. The Columbia (K080386) and Uni-Patch (K915333) electrodes were included in the dispersion testing for comparison purposes. Additional comparison testing to predicate device electrodes was performed to demonstrate suitability of use for each example of electrical stimulation current applications given in the Indications for Use. Both electrical impedance testing and electrical impedance uniformity testing was performed on AMPCARE electrodes as well as predicate device electrodes to demonstrate substantial equivalence.
Conclusion:	*AMPCARE* considers the *AMPCARE 50709 Series Electrodes* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, non-clinical test results, and established medical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 15 2012

AMPCARE, LLC
% Ms. Diane Rutherford
Submissions Manager
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, TX 75080

Re: K121483
Trade/Device Name: AMPCARE 50709 Series Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Electrode, cutaneous
Regulatory Class: Class II
Product Code: GXY
Dated: September 13, 2012
Received: September 14, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: **K121483**

Device Name: AMPCARE 50709 Series Electrodes

Indications for Use:

AMPCARE 50709 Series of cutaneous electrodes are intended to be used to apply electrical stimulation current to the patient's skin. Example electrical stimulation current applications of these electrodes are:

a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief

b) Electrical muscle stimulation (EMS) for neck muscle stimulation.

c) Functional electrical stimulation (FES)

d) Galvanic stimulation.

e) Microcurrent electrical nerve stimulation (MENS).

f) Interferential (IF) stimulation.

g) Neuromuscular electrical stimulation (NMES), including for muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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